K013810

NOV 2 7 2001

7. Premarket Notification 510(k) Summary

a. Submitter:

W. L. Gore and Associates, Inc.
1901 Barksdale Rd.
Newark, DE 19711

Phone: 800-441-7404

Contact: Tracy Wolf

Date Prepared: October 17, 2001

b. Name of Device:

Trade Name: Cardiovascular Array

Common Name: MRI Surface Coil

Device Name: Coil, Magnetic Resonance, Speciality

c. Identification of Predicate Devices:

The GE Cardiac Array is the predicate device which was found to be substantially equivalent through the premarket notification process. These are both receive only, phased array surface coils, designed for use with GE Signa® 1.5T MRI Systems.

d. Description of the Applicant Device:

The Cardiovascular Array is a receive only phased array coil, consisting of an anterior and a posterior "paddle." The phased array design includes 10 elements in a flexible coil, which conforms to different body sizes. The coil produces high resolution images with GE Signa® 1.5T MRI Systems.

e. Intended Use:

The Cardiovascular Array is intended for multiple imaging applications with GE Signa® 1.5T MRI Systems. Its large field of view will allow for images of the complete thorax, including the heart, and its associated vasculature, the abdomen, pelvis, spine and extremities. A specialized sub-array will provide high resolution images of the thoracic region. The predicate device is used to image the same areas of anatomy, but must be repositioned on the patient, between images. The Cardiovascular array with its large field of view can image these areas without repositioning.

The Cardiovascular Array is substantially equivalent to the predicate device with regard to intended use, by imaging a variety of anatomical locations using phased array, receive only surface coils. The descriptive information and performance data contained within this Premarket Notification submission are sufficient to demonstrate substantial equivalence of the applicant device (Cardiovascular Array) to the predicate device (GE Cardiac Array).

f. Technical Characteristics

The Cardiovascular Array uses the same mode of operation, a receive only coil, as the predicate device. It utilizes active decoupling as does the predicate device. The Cardiovascular Array further enhances patient safety by including passive decoupling, and the MR safe cable.

The materials are similar, the patient contact areas for both the applicant and predicate devices, are composed of a biocompatible closed cell polyethylene foam.

In summary, the Cardiovascular Array (applicant) and the GE Cardiac Array (predicate) utilize similar technology and materials. There are no patient safety concerns raised as a result of the clearance of the Cardiovascular Array.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2001

W.L. Gore & Associates, Inc.
c/o Mr. Mark Job
TUV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K013810
Trade/Device Name: Cardiovascular Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 13, 2001
Received: November 15, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K013810

510(k) Number (if known): K013810

Device Name: Coil, Magnetic Resonance, Speciality

Indications For Use:

The Cardiovascular Array is intended for multiple imaging applications with GE Signa(R) 1.5T MRI Systems. Its large field of view will allow for images of the complete thorax, including the heart, and its associated vasculature, the abdomen, pelvis and spine. A specialized sub-array will provide high resolution images of the thoracic region.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013810

(Optional Format 3-10-98)

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